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(Date)

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Applicant : Kalthoff et al.
Serial No. : 10/813,918
Filed : March 31, 2004
Title : SECURE NETWORK GATEWAY FOR ACCESSIBLE
PATIENT DATA AND TRANSPLANT DONOR DATA
Docket No. : LDT01-GN001
Examiner : Lindsey, Rodney M.
Art Unit : 3621

Hon. Commissioner for Patents
Alexandria, VA 22313-1450

ATTENTION: Special Program Examiner, TC 3600

Sir:

PETITION TO MAKE SPECIAL FOR A NEW APPLICATION UNDER M.P.E.P.
§ 708.02, VIII

Applicants hereby petition to make this new application, which has not received any examination by the Examiner, special.

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If the Office determines that all the claims presented are not obviously directed to a single invention, then Applicants will make an election without traverse as a prerequisite to the grant of special status.

Applicants submit that a pre-examination search has been carried out for domestic and foreign patent references related to the field of endeavor of the present invention.

The field of search was directed to the following areas:

<u>Class</u>	<u>Class Identifier</u>	<u>Database</u>
705	Data Processing	U.S., EPO

Applicants' attorney has supplemented this search with an on-line search of the United States Patent and Trademark Office patent database, as well as the databases of the European Patent Office related to the field of endeavor of the present invention.

Copies of the references developed in these pre-examination searches are submitted herewith along with an Information Disclosure Statement and associated forms.

Summary of the Present Invention and Claims

The present invention is related to information systems and network systems and, more specifically, to organ and/or tissue transplant information systems and organ and/or tissue network systems utilized by hospitals, organ and/or tissue procurement organizations, transplant centers, and the like. The present invention reduces the time to disseminate organ and tissue transplant information and allows multiple parties to view the same transplant data concurrently, without compromising the secure nature of the gateway through which the data is accessed. In one exemplary embodiment of the present invention, an Organ Transplant Response System (OTRS) automates the organ and tissue placement process and streamlines the notification, verification, and matching of potential transplantable organs and tissue with potential transplant recipients, thereby saving countless lives by enabling more organs and tissue to be placed from the (already

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consented) organ donors and by increasing the quantity, quality, and speed of donor data and/or donor images communicated to intended third parties.

The system in a more detailed exemplary embodiment includes a client application and a server application operative to pass files from a client computer to a server computer via dial-up modem/landline, Ethernet connection, or through a wireless card or computer-phone or smart phone capable of handling data transmission. As wireless transmission speeds and wireless device capability expands, so too will the capability of the present invention.

OTRS, in addition to accommodating electronic donor information, may also accommodate electronic transplant recipient information and include software to identify and display potentially matching and potentially exclusionary items in order to assist in the match of donor and recipient data. Such a dual data source allows the transplant surgeon to review medical data comparing their patient and the donor all in the same or in different computer systems. Thus, an increased number of organs and/or tissue are accepted, with increased speed of acceptance and with a heightened post-operative condition for the transplant recipient. The entire process utilizing the OTRS may be paperless or include one or more hardcopies that may be amendable to digital scanning or other electronic data storage technique.

The OTRS system may also include a qualitative and quantitative tracking aspect to enable long term monitoring of donor recipients and the placement and success rates of transplant centers. The OTRS system may further include a searchable database feature to enable an intended third party to search donor records and review those records most relevant to a particular set of circumstances.

Independent claim 1 of the instant application is directed to a method of accessing transplant donor data from a remote location, the method comprising the steps of: (i) accessing a database over a network containing transplant donor data that includes information specific to a potential transplant donor; (ii) reviewing the information specific to the potential transplant donor; and (iii) acting on the transplant donor data reviewed to establish qualification to at least one of an organ and a tissue available for transplant.

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Independent claim 23 is directed to a method of gathering and inputting transplant donor data to a database, the method comprising the steps of: (i) compiling a transplant donor record specific to a transplant donor; (ii) accessing a remote database capable of storing a plurality of transplant donor records; and (iii) uploading the transplant donor record to the remote database.

Independent claim 45 is directed to a method of gathering and displaying transplant donor data, the method comprising the steps of: (i) compiling a transplant donor record specific to a transplant donor; (ii) transmitting an electronic version of the transplant donor record; and (iii) displaying the transplant donor record using the electronic version of the transplant donor record.

Independent claim 49 is directed to a method of organizing and making available transplant donor data, the method comprising the steps of: (i) providing a secure database to store transplant donor data; (ii) providing access to a selective third party to at least one of upload and view transplant donor data and download and view transplant donor data; and (iii) generating an authorization code required to access the transplant donor data by the selective third party.

Independent claim 72 is directed to a method of gathering and inputting transplant donor data to a database in the form of a pure data system, the method comprising the steps of: (i) providing a series of data input options into which transplant donor data may be input to create an transplant donor record, the series of data input options including at least one of edit transplant donor data, update transplant donor data, delete transplant donor data, and submit transplant donor data; (ii) inputting transplant donor data into at least one of the series of data input options to create the transplant donor record; (iii) transmitting the transplant donor record to an transplant donor database; and (iv) availing the transplant donor record via the Internet.

Independent claim 76 is directed to a transplant information system to facilitate the dissemination of information pertaining to transplantable organs and tissue from a donor hospital to a transplant center, the system comprising: (i) a database accessible by a procurement organization representative and a transplant center representative, the database including transplant donor data; and (ii) a secure network through which the

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transplant donor data is accessed by at least one of the procurement organization representative and the transplant center representative.

Discussion of the References Submitted in the IDS

WIPO Published Patent Application No. WO01/70094 to Ferguson et al.

appears to disclose a chronic patient management system for developing a patient data record for use in managing the medical care of chronically ill patients. The data related to the patient that may be collected and reviewed includes patient data, clinical data, and administrative data. In a preferred embodiment of the invention, transplant related information for patients is collected, monitored, and reported. An interface component, an administrator component, a pre-transplant component, and a post-transplant component support the entry and review of data that is particularly important in managing care for transplant patients. Healthcare professionals from many different disciplines can access the patient management system and view the data in a manner that is appropriate for each person's area of expertise.

Ferguson is concerned with a patient information database and, more specifically, with a database amendable to track patients before and after an organ transplant surgery. Ferguson utilizes this database to determine eligibility for a transplantable organ and update the physician on the conditions related to the potential recipient. Ferguson does briefly discuss that cadaveric donor data may be entered into the system, however, Ferguson indicates that this information is "minimal and very confidential." (p. 13, l. 20). In other words, Ferguson does not envision a system that is directed specifically to transplant donor data, nor a system that includes at least a majority of the transplant donor data fields necessary to determine whether a potential organ donor is eligible for donating one or more organs.

Independent claim 1 is patentable over Furguson, at least in part, because Furguson fails to disclose reviewing information specific to a potential transplant donor, as well as acting on the specific transplant donor data reviewed to establish qualification to at least one of an organ and a tissue available for transplant.

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Independent claim 23 is patentable over Furguson, at least in part, because Furguson fails to disclose compiling a transplant donor record specific to a transplant donor, as well as uploading the transplant donor record to a remote database.

Independent claim 45 is patentable over Furguson, at least in part, because Furguson fails to disclose compiling a transplant donor record specific to a transplant donor, as well as displaying the transplant donor record using the electronic version of the transplant donor record.

Independent claim 49 is patentable over Furguson, at least in part, because Furguson fails to disclose providing access to a selective third party to at least one of upload and view transplant donor data and download and view transplant donor data, as well as generating an authorization code required to access the transplant donor data by the selective third party.

Independent claim 72 is patentable over Furguson, at least in part, because Furguson fails to disclose providing a series of data input options into which transplant donor data may be input to create an transplant donor record, the series of data input options including at least one of edit transplant donor data, update transplant donor data, delete transplant donor data, and submit transplant donor data, as well as availing the transplant donor record via the Internet.

Independent claim 75 is patentable over Furguson, at least in part, because Furguson fails to disclose a method of gathering transplant donor data, where a computer is operatively coupled to a scanner and the computer has at least one electronic transplant donor form adapted to be manipulatable to input transplant donor data using at least one of keystrokes, digital handwriting, and scanned images.

Independent claim 76 is patentable over Furguson, at least in part, because Furguson fails to disclose a database accessible by a procurement organization representative and a transplant center representative, the database including transplant donor data, as well as a secure network through which the transplant donor data is accessed by at least one of the procurement organization representative and the transplant center representative.

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WIPO Published Patent Application No. WO03/081386 to Zeltzer et al.

appears to disclose a system and method for storing personal, medical, and insurance related information on a wireless device. The information may be stored by sending it from a remote personal computer to a central database using the Internet. The information may be temporarily stored on the central database and password protected. The information is thereafter downloaded from the central database to the wireless device, where it is permanently stored. The information then may be deleted from the central database so that it is secured on the wireless device. All or portions of the information stored on the wireless device may be password protected. The information may be accessed on the wireless device (e.g., on a display) or sent from the wireless device to remote locations, such as a doctor's office or hospital. Zeltzer is concerned with storing personal, medical, and insurance data on a wireless device, however, Zeltzer is not concerned with transmitting and saving organ and/or tissue transplant donor data to a wireless device.

Independent claim 1 is patentable over Zeltzer, at least in part, because Zeltzer fails to disclose accessing a database over a network containing transplant donor data that includes information specific to a potential transplant donor, reviewing the information specific to the potential transplant donor, and acting on the transplant donor data reviewed to establish qualification to at least one of an organ and a tissue available for transplant.

Independent claim 23 is patentable over Zeltzer, at least in part, because Zeltzer fails to disclose compiling a transplant donor record specific to a transplant donor, accessing a remote database capable of storing a plurality of transplant donor records, and uploading the transplant donor record to the remote database.

Independent claim 45 is patentable over Zeltzer, at least in part, because Zeltzer fails to disclose compiling a transplant donor record specific to a transplant donor, transmitting an electronic version of the transplant donor record, and displaying the transplant donor record using the electronic version of the transplant donor record.

Independent claim 49 is patentable over Zeltzer, at least in part, because Zeltzer fails to disclose providing a secure database to store transplant donor data, providing

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access to a selective third party to at least one of upload and view transplant donor data and download and view transplant donor data, and generating an authorization code required to access the transplant donor data by the selective third party.

Independent claim 72 is patentable over Zeltzer, at least in part, because Zeltzer fails to disclose providing a series of data input options into which transplant donor data may be input to create an transplant donor record, the series of data input options including at least one of edit transplant donor data, update transplant donor data, delete transplant donor data, and submit transplant donor data, inputting transplant donor data into at least one of the series of data input options to create the transplant donor record, transmitting the transplant donor record to an transplant donor database, and availing the transplant donor record via the Internet.

Independent claim 75 is patentable over Zeltzer, at least in part, because Zeltzer fails to disclose utilizing a computer operatively coupled to a scanner, where the computer has at least one electronic transplant donor form adapted to be manipulatable to input transplant donor data using at least one of keystrokes, digital handwriting, and scanned images, and the computer includes software to facilitate the uploading of the transplant donor data to a remote database over a network connection, the remote database including a remote digital processing device, such that the remote database is accessible by an intended third party.

Independent claim 76 is patentable over Zeltzer, at least in part, because Zeltzer fails to disclose a database accessible by a procurement organization representative and a transplant center representative, the database including transplant donor data, and a secure network through which the transplant donor data is accessed by at least one of the procurement organization representative and the transplant center representative.

U.S. Patent No. 5,241,466 to Perry et al. appears to disclose a central depository for secure storage and rapid retrieval of important documents and information, such as living wills, durable powers of attorney, testamentary wills, authorization for organ donation, authorization of bone marrow donation, and insurance information. The depository includes a data storage facility having a computer and Write Once, Read Many (WORM) drive CD-ROM player connected to an optical scanner. The documents

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are scanned by the optical scanner and stored on the CD-ROM player. Other information is entered into data storage facilities connected to the computer. Requests for information can be received by the depository from remote locations by data transmission devices, such as telephone, facsimile, postal service, or electronic mail. The system also provides a procedure for updating the information and documents as legislation regarding the stored information and documents changes. Also, the system monitors for changes in residence that may affect the information and documents. Perry is concerned with long-term management of legal documents, but is not concerned with short-term management of organ or tissue donor data obtained from the potential transplant donor necessary to determine whether a potential organ donor is eligible for donating one or more organs.

Independent claim 1 is patentable over Perry, at least in part, because Perry fails to disclose reviewing information specific to a potential transplant donor and acting on the transplant donor data reviewed to establish qualification to at least one of an organ and a tissue available for transplant.

Independent claim 23 is patentable over Perry, at least in part, because Perry fails to disclose compiling a transplant donor record specific to a transplant donor, accessing a remote database capable of storing a plurality of transplant donor records, and uploading the transplant donor record to the remote database.

Independent claim 45 is patentable over Perry, at least in part, because Perry fails to disclose compiling a transplant donor record specific to a transplant donor, transmitting an electronic version of the transplant donor record, and displaying the transplant donor record using the electronic version of the transplant donor record.

Independent claim 49 is patentable over Perry, at least in part, because Perry fails to disclose providing a secure database to store transplant donor data, providing access to a selective third party to at least one of upload and view transplant donor data and download and view transplant donor data, and generating an authorization code required to access the transplant donor data by the selective third party.

Independent claim 72 is patentable over Perry, at least in part, because Perry fails to disclose providing a series of data input options into which transplant donor data may be input to create an transplant donor record, the series of data input options including at

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least one of edit transplant donor data, update transplant donor data, delete transplant donor data, and submit transplant donor data, inputting transplant donor data into at least one of the series of data input options to create the transplant donor record, transmitting the transplant donor record to an transplant donor database, and availing the transplant donor record via the Internet.

Independent claim 75 is patentable over Perry, at least in part, because Perry fails to disclose utilizing a computer operatively coupled to a scanner, where the computer has at least one electronic transplant donor form adapted to be manipulatable to input transplant donor data using at least one of keystrokes, digital handwriting, and scanned images, and the computer includes software to facilitate the uploading of the transplant donor data to a remote database over a network connection, the remote database including a remote digital processing device, such that the remote database is accessible by an intended third party.

Independent claim 76 is patentable over Perry, at least in part, because Perry fails to disclose a database accessible by a procurement organization representative and a transplant center representative, the database including transplant donor data, and a secure network through which the transplant donor data is accessed by at least one of the procurement organization representative and the transplant center representative.

U.S. Patent No. 5,993,387 to Moore et al. appears to disclose a computer-based mixed-use cord stem cells registry system for developing and maintaining a mixed-used bank of placental and umbilical cord stem cells and for the resultant bank. The cord stem cells, or a fraction thereof, are stored in a bank for the potential use of the donor child and potentially the actual family of the donor child or from an unrelated person for whom the cord stem cells are a match. The system makes the cord stem cells available to the family until the blood sample is found to match a non-family member in need of the cord stem cells. At this time the family is given an option of keeping the sample for themselves or of providing it to the non-family member along with current information on the donor family. Moore is concerned with a stem cell registry system, but is not concerned with organ or tissue transplant donor data.

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Independent claim 1 is patentable over Moore, at least in part, because Moore fails to disclose accessing a database over a network containing transplant donor data that includes information specific to the potential transplant donor, reviewing information specific to a potential transplant donor, and acting on the transplant donor data reviewed to establish qualification to at least one of an organ and a tissue available for transplant.

Independent claim 23 is patentable over Moore, at least in part, because Moore fails to disclose compiling a transplant donor record specific to a transplant donor, accessing a remote database capable of storing a plurality of transplant donor records, and uploading the transplant donor record to the remote database.

Independent claim 45 is patentable over Moore, at least in part, because Moore fails to disclose compiling a transplant donor record specific to a transplant donor, transmitting an electronic version of the transplant donor record, and displaying the transplant donor record using the electronic version of the transplant donor record.

Independent claim 49 is patentable over Moore, at least in part, because Moore fails to disclose providing a secure database to store transplant donor data, providing access to a selective third party to at least one of upload and view transplant donor data and download and view transplant donor data, and generating an authorization code required to access the transplant donor data by the selective third party.

Independent claim 72 is patentable over Moore, at least in part, because Moore fails to disclose providing a series of data input options into which transplant donor data may be input to create an transplant donor record, the series of data input options including at least one of edit transplant donor data, update transplant donor data, delete transplant donor data, and submit transplant donor data, inputting transplant donor data into at least one of the series of data input options to create the transplant donor record, transmitting the transplant donor record to an transplant donor database, and availing the transplant donor record via the Internet.

Independent claim 76 is patentable over Moore, at least in part, because Moore fails to disclose a database accessible by a procurement organization representative and a transplant center representative, the database including transplant donor data, and a

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secure network through which the transplant donor data is accessed by at least one of the procurement organization representative and the transplant center representative.

Remaining References

The remaining prior art references listed in the attached Information Disclosure Statement are only marginally related to the claimed invention, or are redundant with respect to one or more of the references discussed above. Therefore, a discussion of each of these references has been omitted for purposes of brevity.

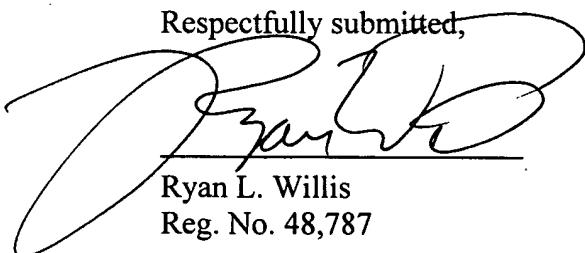
Conclusion

Applicants respectfully submit that the requirements for granting special status in the above-identified application, having received no substantive examination on the merits by the Examiner, in accordance with MPEP § 708.02 VIII have been met in toto in the instant petition. Therefore, Applicants request that special status for the instant application be granted.

A check in the amount of \$130.00 required by 37 C.F.R. 1.17(h) is also included herewith.

If the Examiner has any questions regarding this petition, please do not hesitate to contact the undersigned at the telephone number provided below.

Respectfully submitted,



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